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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,576	11/06/2000	Charles L. Magness	55382-3	9656

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EXAMINER	
SKIBINSKY, ANNA	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/707,576	MAGNESS ET AL.	
	Examiner	Art Unit	
	Anna Skibinsky	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14-26,28,31-44 and 46-55* is/are pending in the application.

4a) Of the above claim(s) *56-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,14-26,28,31-44 and 46-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Claim Amendments

Amendments to claims 1, 20, and 49-51 are acknowledged.

Newly submitted claims 56-61 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 1-55 are toward a computer implemented method for the identification of a drug target associated with a biological condition. Newly submitted claims 56-61 recite a computer implemented method for the classification of a population for evaluation of a biological condition. The result of the original claims is distinct from the result of the newly submitted claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56-61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

The affidavit under 37 CFR 1.132 filed 02/24/2006 is insufficient to overcome the rejection of claims (all) based upon 135 USC § 112, first paragraph, as set forth in the last Office action because:

Dr. Shawn Iadonato is of extraordinary skill in the art (Affidavit, points 1, 2, and 3). 112, 1st requires any person of skill in the art to be able to make and use in the invention. As such, the affidavit demonstrates only one of extraordinary skill in the art would be able to make and use the invention.

The affidavit does not establish when the disclosed procedures and experimentation were performed. As such, the affidavit does not demonstrate that the claimed invention was enabled at the time of filing in the instant application.

The disclosed procedures and experimentation in the affidavit required the use of a URU population (Affidavit page 2, point 7, line 2). Independent claims 1, 20, and 41) do not recite any requirement for the use of a URU population.

The instant claims are broad in that they are drawn to identifying a drug target associated with a disease, without any limitation to what disease is targeted. The affidavit supports only the identification of a drug target for hepatitis C.

Claim Rejections - 35 USC § 101

Claims 1-19, 47, 49, 50, and 51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Said claims are toward a computer implemented method involving the classification of medical data of populations and the identification of a drug target. Though the properties calculated by the model are physical properties, the data is nontheless generated within a computer without a physical manifestation such as the transfer of data between a memory and a processor, a physical step such as the

obtaining of a sample or, the visual display of results. Thus, these claims do not produce a result which meet the standard of being concrete, tangible and useful.

The claims "must be for a practical application of the abstract idea, law of nature, or natural phenomenon. Diehr, 450 U.S. at 187, 209 USPQ at 8 ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); Benson, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

1) The claimed invention "transforms" an article or physical object to a different state or thing.

2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed in MPEP 2106, and See also:

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

The manipulation of coordinates and interaction energies or residues to calculate the crossover point is the manipulation of numbers, performed by the computer implementing programs and is therefore nonstatutory subject matter. Manipulation of data does not include a physical transformation outside of a computer or representation thereof. A process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and is not deemed to be concrete, tangible, and useful and is therefore non-statutory. An example which would make the instant method steps statutory would be to include a

step of displaying the data for a user. Hence, the data would become concrete, tangible, and useful.

Claim Rejections - 35 USC § 112-1st Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

ENABLEMENT

2. Claims 1-10, 14-26, 28, 31-44 and 46-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In re Wands (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to use the claimed invention one of skill in the art must identify a drug

target for any selected biological condition from data related to identified genetic variations between ARA and ARAU subpopulations. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The disclosure (see for example, page 25, line 19 through page 30, line 8) sets forth steps that are taken to analyze a population and define affected status, risk factors, and the characterization of the ARA, ARU, and URU phenotypes. The disclosure does not provide any guidance as to what procedures or practices using identified genetic variations between ARA and ARAU subpopulations that result in the identification of a drug target for any given biological condition.

c) The disclosure does not provide any examples wherein a drug target was identified.

d) The nature of the invention, drug target identification, is complex.

e) The prior art shows studies of hepatitis C, however the genetic basis for any disease has not been studied and therefore can not provide guidance of where on the genetic code the mutations of interest would exist. The prior art is silent in regards to methods or procedures wherein a drug target associated with any given biological condition is identified through data related to genetic variations between ARA and ARU subpopulations, wherein no prior knowledge of a relationship between said target and said biological condition is available.

f) The skill of those in the art of drug target identification is high.

g) The predictability of identifying a drug target for any given biological condition

from data related to genetic variances unknown in the prior art.

h) The claims are broad in that they are drawn to identification of a drug target for any given biological condition from any data related to genetic variances unknown in the prior art.

The skilled practitioner would first turn to the instant disclosure for guidance in using the claimed invention. However, the disclosure lacks clear evidence that any drug target for any given biological condition has been identified using data related to genetic variances. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not discuss methods or procedures wherein a drug target associated with any given biological condition is identified through data related to genetic variations between ARA and ARU subpopulations, wherein no prior knowledge of a relationship between said target and said biological condition is available. Finally, said practitioner would turn to trial and error experimentation to determine a drug target for a given biological condition using said data. Such amounts to undue experimentation.

The claims in the instant application to identifying the drug target associated with a selected biological condition by comparing the variations between which is deemed as being not enabled in the instant application.

Applicants state (page 27, lines 6-9, of the Remarks) that the present application provides extensive guidance to allow one of ordinary skill in the art to obtain a polypeptide that is within the scope of the claims and by following the guidance, applicants have developed such a target and a drug.

The application recites (page 10, line 26 to page 11, line 10) the use of PCR to amplify the coding regions of each candidate gene and then comparing each patient's candidate gene sample sequence to a reference sequence to identify all sequence mutations and variants. After taking the DNA samples, the process of isolating the coding region pertinent to the disease of interest is not described and thus applicants have not described how to identify where the genetic variation associated with the disease exists. The claimed invention does not include prior knowledge of where to look for the coding region of interest and the claim is broader the Applicant's own example which includes locating a target gene for hepatitis C (Remarks, page 28, 3rd paragraph; and page 30, 2nd paragraph). Studies hepatitis C exist which predate the instant applications. However, the genetic basis for many disease have not been studied and can not provide guidance of where on the genetic code the mutations of interest would exist. Without prior knowledge, finding the difference for two populations, as pertaining to a specific genetic trait requires vast undue experimentation and is not enabled in the instant application.

Applicants state (Remarks, page 27, lines 6-9) that the present applicants provide extensive guidance to allow one of ordinary skill in the art to obtain a polypeptide. This is not persuasive because a polypeptide is not a drug target. Furthermore, in the discussion of classification of populations, followed by PCR, then DNA sequence analysis, followed by detection of the mutation (specification, page 10, line 22 to page 11, line 25), it is not disclosed how the relevant polynucleotide is

detected. Additionally, how the functional coding region carrying the genetic difference of interest is located and determination of whether it is a drug target is not described.

Applicants state (Remarks, page 28, last paragraph) that Dr. Iadonato attests to the conclusion that when the guidance of he specification is followed, a target and drug are identified. This is not persuasive because the specification does no disclose specifically how to obtain the drug target, or example how one determines which regions in the genome encode for the receptor that leads to a treatment.

Applicants state (Remarks, page 29, lines 1-2) that working examples are provided on pages 30-34 of the specification. Upon examination, no working examples are found for the identification of a drug target. Pages 30-34 are further descriptions of how to collect and classify data of the populations. The section is titled "Individual Subject Analysis and Classification". Lines 14-16 of page 34 recite "the knowledge gained from this genetic analysis can also form the basis for diagnostic assay or vaccine development." However, specific examples of how one would use the genetic analysis to forma a vaccine or identify a drug target are not taught.

Applicants state (Remarks, page 31, 2nd paragraph) that Examiner has provided no evidence that the claimed methods would be more difficult and unreliable than known methods.

In the previous Office Action, Examiner did not allege that "claimed methods would be more difficult and unreliable than known methods."

There is undue experimentation required to go from the classification results achieved by implementing the invention to drug target identification without some prior

knowledge of a relationship between a potential target and a biological condition as claimed. The specification provides descriptions for the collecting and scoring of data from the population to achieve the final classification of sub-populations in ARU, ARA, and URA. However, the details for identifying a drug target based on the classification are not described. Thus, there is not sufficient support to enable one skilled in the art of make or use the invention. The specification recites (page 13, lines 16-20), "As those skilled in the art can appreciate, this type of genotypic evaluation is significant within the present invention due to the classification of subjects into the phenotypic categories discussed above. That is, the discovery of genetic drug targets become a valuable tool when the ARU phenotype is compared against other sub-population." Though the statement points out the usefulness of the described classification method for the identification of drug targets, it does not specifically describe the invention as containing a method for identifying drug targets nor does it describe the method, experimental or computational, for identifying drug targets. The identification of a drug target requires the sorting out of 1000's of targets present in most organisms. Because the method of identifying a drug target based on genetic differences between two groups is not trivial and requires years to complete by someone skilled in the art, the general mention of the method in the specifications of the instant application does not provide sufficient guidance.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The rejection of claims 1-10, 14-19 and 47-55 for being Vague and Indefinite in the Office Action filed August 29, 2005 is withdrawn.

Claim Rejections – 35 USC § 102

The rejection of claims 1-10, 14-26, 28, 31-44, and 46-55 over the NIH's risk assessment models in the Office Action filed August 29, 2005 is withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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